

PATENT

Customer No. 22,852 Attorney Docket No. 06843.0035-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jean-Michel DAYER et al.

Serial No.: 09/803,918

Filed: March 13, 2001

PECEIVED

Group Art Unit: 1644

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Examiner: M. Jamroz TECH CENTER 1600/2900

Commissioner for Patents and Trademarks Washington, DC 20231

APO-A-I REGULATION OF T-

CELL SIGNALING

Sir:

For:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed April 8, 2002, the Examiner required restriction under 35 U.S.C. § 121 between the following Groups. A petition for a three-month extension of time and the requisite fee are filed herewith.

Group I: claims 1-8, 11-13, and 44-45, allegedly drawn to a nucleic acid, vector, host cell, and a process for making an apo-A-I fragment polypeptide;

Group II: claims 9, 10, 15-17, 36-43, and 46-49, allegedly drawn to a polypeptide, fragments thereof, compositions thereof, and fusion proteins thereof having the sequence SEQ ID NO: 2;

Group III: claims 18-28 and 30-34, allegedly drawn to an antibody or selective binding agent that binds to a polypeptide having the sequence SEQ ID NO: 2, and a hybridoma;

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Group IV: Claim 14, allegedly drawn to a method of determining whether a compound inhibits AFTI polypeptide activity or production;

Group V: Claim 29, allegedly drawn to a method of detecting or quantifying the amount of AFTI polypeptide in a sample with an antibody;

Group VI: Claim 35, allegedly drawn to a method for treating, preventing, or ameliorating a disease, condition, or disorder comprising administering a selective binding agent that binds to a polypeptide having the sequence SEQ ID NO: 2;

Group VII: Claims 59-61, allegedly drawn to a method for treating, preventing, or ameliorating a disease, condition, or disorder involving monocyte activation comprising administering apo-A-I, a fragment thereof, or a fusion protein comprising SEQ ID NO: 2;

Group VIII: Claims 50-51, allegedly drawn to a method for reducing inflammation comprising administering SEQ ID NO: 2 or fragments thereof;

Group IX: Claims 52, 53, 56, and 57, allegedly drawn to a method for reducing IL-1-β secretion comprising administering SEQ ID NO: 2 or fragments thereof; and

Group X: Claims 54, 55, and 58, allegedly drawn to a method for reducing TNF-α secretion comprising administering SEQ ID NO: 2 or fragments thereof.

RESPONSE

Applicants elect to prosecute Group II, claims 9, 10, 15-17, 36-43, and 46-49 with traverse.

According to the Office, Groups I-III are different products. (Office Action mailed April 8, 2002, page 3.) The Office asserts that "nucleic acids, polypeptides, and

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antibodies differ with respect to their structures and physicochemical properties" and "therefore each product is distinct." (*Id.*)

According to MPEP § 803, there are two requirements that must be met before a proper Restriction Requirement may be made. These two requirements are: "The inventions must be independent . . . or distinct as claimed; and there must be a serious burden on the Examiner if restriction is required . . ." (emphasis added).

Applicants respectfully submit that the Office has failed to satisfy the second requirement set forth in MPEP § 803 with respect to Groups I and II, and that restriction between those groups is therefore improper. The claims in Group I recite, *inter alia*, nucleic acids encoding portions of a peptide having sequence SEQ ID NO: 2, vectors and cells comprising these nucleic acid sequences, and a process for making portions of a peptide having sequence SEQ ID NO: 2 using these nucleic acids, vectors, and host cells. The claims of Group II recite, *inter alia*, the peptides made by the processes of Group I using the nucleic acids, vectors, and host cells of Group I.

The Office has failed to establish or even allege that a serious burden exists on the Examiner if restriction is not required between the claims of Groups I and II.

Applicants respectfully submit that a search of the subject matter of Groups I and II would not be burdensome, because a search of the subject matter of Group I should encompass a search of the subject matter of Group II since all of the claims recite polypeptide fragments or nucleic acids encoding polypeptide fragments of SEQ ID NO:

2. Moreover, Groups I and II are linked by the cross-references in claims 9 and 10 (Group II) to claims in Group I. The search and examination of Group II should

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therefore substantially overlap a search for the subject matter of Group I, and a serious burden to examine both Groups together would not exist.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: August 7, 2002

William L. Strauss

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